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PATENT
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IN THE UNITED STATE PATENT AND TRADEMARK OFFICE

In re Application of:)
Tamotsu Kataoka et al.)
Serial No.: 09/857,898) Group Art Unit:1772
Filed: June 13, 2001) Examiner: Simone, Catherine A
For: MULTILAYERED FILM AND CONTAINER)

Assistant Commissioner for Patents
Washington, DC 20231
Sir:

RULE 132 DECLARATION

I, Tamotsu Kataoka do hereby declare that I am one of the inventors of the above-identified application and that I am a citizen of Japan, residing at 146, Aza Miyanonishi, Kitahama, Muya-cho, Naruto-shi, Tokushima 772-0015, Japan. That I graduated in chemistry at Okayama University of Science in 1977. That I have been employed by the OTSUKA PHARMACEUTICAL FACTORY, INC., a Japanese Corporation and the assignee of record of the above-identified application, since 1977. That recently I have been engaged in research activities relating to the development of materials for medical containers at Technical Department of Matsushige Factory of OTSUKA PHARMACEUTICAL FACTORY, INC.. I am familiar with the history of prosecution of this application and specifically the Examiner's opinion raised in the final Office Action dated March 7, 2003 that Claims 1 to 8 are unpatentable over Watanabe (EP 0 699 521) in view Watanabe et al. (US 5,478,617) under 35 U.S.C § 103.

To show that the claimed multilayered film and container are never identical with those disclosed in the cited references, and that claimed multilayered film and container have outstanding features that are not found in the prior art references, I conducted experiments as set forth below.

Experiment

[1] Object of experiments

The object is to prepare each of containers using the multilayered film according to the invention claimed in U.S. Patent Application No.09/857,898 and the multilayered film as set forth in EP 0699521 to compare each quality thereof.

[2] Materials for experiments

(a) Constituent elements of resins

Components constituting a resin and a mixed resin used in the following experiments are as follows:

- Ethylene · α-olefinic copolymer

(1) Ethylene · 1-butene copolymer [manufactured by MITSUI CHMICALS, INC., density = 0.920g/cm^3, MFR=2.1g/10 minutes (190°C)]

- Ethylene · α-olefineic elastomer

(2) Ethylene · 1-butene copolymer elastomer [manufactured by MITSUI CHEMICALS, INC., density = 0.885g/cm^3, MFR = 0.5 g/10 minutes (190°C)]

- High-density polyethylene

(3) Ethylene · 1-butene copolymer [manufactured by MITSUI CHEMICALS, INC., density = 0.962g/cm^3, MFR = 15 g/10 minutes (190°C)]

- Polypropylene

(4) Isotactic polypropylene (ethylene content: 5% by weight or less) [manufactured by MITSUI CHEMICALS, INC., density = 0.910g/cm^3, MFR = 1.6 g/10 minutes (230°C)]

(b) Constituent elements of multilayered films

- Resin (A):

Ethylene · α-olefinic copolymer

A-1: Ethylene · 1-butene copolymer [manufactured by MITSUI CHEMICALS, INC., density = 0.940g/cm^3, MFR = 2.1g/10 minutes (190°C)]

- Mixed Resin (B):

B-1: Mixed resin comprising 45% by weight of the copolymer (1), 50% by weight of the elastomer (2) and 5% by weight of the high-density polyethylene (3) (density of mixed resin = 0.906g/cm^3)
B-2: Mixed resin comprising 45.5% by weight of the copolymer (1), 50% by weight of the elastomer (2) and 4.5% by weight of the high-density polyethylene (3) (density of mixed resin = 0.905g/cm^3)

- Mixed resin (C):

C-1: Mixed resin comprising 45% by weight of the polypropylene (4), 50 % by weight of the elastomer (2) and 5% by weight of the high-density polyethylene (3)
C-2: Mixed resin comprising 41.5% by weight of the polypropylene (4), 53.5 % by weight of the elastomer (2) and 5% by weight of the high-density polyethylene (3)
C-3: Mixed resin comprising 30% by weight of the polypropylene (4), 65 % by weight of the elastomer (2) and 5% by weight of the high-density polyethylene (3)
C-4: Mixed resin comprising 45% by weight of the polypropylene (4), 45 % by weight of the elastomer (2) and 10% by weight of the high-density polyethylene (3)

- Mixed resin (D):

D-1: Mixed resin comprising 45% by weight of the polypropylene (4) and 55 % by weight of the elastomer (2)

[3] Production of multilayered films

Using the resin A-1, and mixed resins B-1, C-1 to C-4 and D-1, multilayered films (1), (2) and (3) having the layer configuration shown in the following Table 1 were respectively produced by a water-cooling coextrusion inflation method.

- Multilayered Film (1): multilayered film as set forth in Example 1 of U.S. Patent Application No.09/857,898
- Multilayered Film (2): film obtained by using the mixed resin B-1 instead of the mixed resin C-1 for the fourth layer in the multilayered film (1)
- Multilayered Film (3): multilayered film as set forth in Example 4 of EP 0 699 521

Table 1

	First layer	Second layer	Third layer	Fourth layer	Fifth layer
Multilayered film (1)	A-1	B-1	A-1	D-1	A-1
	20 μm	100 μm	10 μm	100 μm	30 μm
Multilayered film (2)	A-1	B-1	A-1	B-1	A-1
	20 μm	100 μm	10 μm	100 μm	30 μm
Multilayered film (3)	A-1	B-1	A-1	B-2	A-1
	15 μm	80 μm	10 μm	80 μm	15 μm

[4] Production of container

Using the multilayerd films (1), (2) and (3), medical containers (bags for infusion fluid) 10 [referred to as containers (1), (2) and (3), respectively] having a volume of 500 ml shown in Fig. 1 were produced. Heat sealing of the peripheral portion in the forming of these medical containers 10 was conducted at 155°C for 4.5 seconds, while sealing of a port member 20 was conducted at 140 to 150°C for 3 seconds.

[5] Pinhole Test

The medical containers (bag for infusion fluids) 10 obtained above were filled with physiologic saline, sealed with a rubber stopper, and then subjected to steam sterilization under high pressure at 110°C for 40 minutes. After the completion of the treatment, it was examined whether pinholes were present or not, using a handy electrostatic capacity type pinhole tester [pinhole tester, Model H, manufactured by Densoku Seiko Co., Ltd.]. With respect to the containers wherein sealing of the port member 20 was conducted under three conditions of the temperature of 140°C, 145°C and 150°C, respectively, the examination was conducted under three conditions of the applied voltage of 15 kV, 20 kV and 25 kV, respectively, using ten bags for each condition. That is, 90 bags were examined in total. The above test was conducted under considerably severe conditions as compared with normal production conditions of medical containers. Accordingly, when the proportion of specimens wherein pinholes occurred was smaller than 5% (under five specimens out of 90 specimens), the pinhole resistance would be rated good.

The number of specimens wherein pinholes were found and respective proportions (%) are shown in Table 2.

Table 2

	Container (1)	Container (2)	Container (3)
Number of specimen	90	90	90
Proportion (%)	4.4	40	44

As is apparent from Table 2, the bag for infusion fluids obtained by using the multilayered film (1) is extremely excellent in pinhole resistance because the proportion of specimens wherein pinholes were found is smaller than 5 % even under such severe conditions. On the other hand, the proportions of specimens of the bags for infusion fluids obtained by using the multilayered film (2) and (3) wherein pinholes were found are 40% and 44 % respectively; it is proved that the bags for infusion fluids obtained by using the multilayered film (2) and (3) are inferior to that using the multilayered film (1) in pinhole resistance.

[6] Conclusion

As having much smaller proportion wherein pinholes are found, the container prepared by using the multilayered film according to the invention claimed in U.S. patent application No.09/857,898 is superior to the container prepared by using the multilayered film as set forth in EP 0699521 in quality.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 20, 2003 By: Tamotsu Kataoka

Tamotsu Kataoka

FIG. 1